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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/761,969	01/16/2001	Martha Garrity	A1712	5878

33197 7590 10/13/2004

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EXAMINER
COOK, LISA V

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 10/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/761,969	GARRITY ET AL.	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,11,12,15,17-20,22,25-41 and 85-93* is/are pending in the application.

4a) Of the above claim(s) *86-93* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,11,12,15,17-20,22 and 25-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-7,11,12,15,17-20,22,25-41 and 85-93* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicants' response filed 10/15/03 and supplemental response filed 6/28/04 are acknowledged. Amendments to the specification as well as claims 1, 19, and 85 are noted. New claims 86-93 have been added. Claims 42-84 have been canceled without prejudice. Currently claims 1-7, 11-12, 15, 17-20, 22, 25-41, and 85-93 are pending.

Election/Restrictions

2. Newly submitted claims 86-93 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, 11-12, 15, 17-20, 22, 25-41, and 85 are drawn to a kit for determining vitamin D concentration wherein the kit comprises cyclodextran, sodium salicylate, and NaOH classified in class 422, subclass 61 for example.

II. Claims 86-93 are drawn to a kit for determining vitamin D concentration wherein the kit comprises cyclodextran, sodium salicylate, NaOH, and a plurality of reagents including 25-OH-D coupled to a solid phase, classified in class 422, subclass 61.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

In the instant case each of the kit inventions in Groups I and II are patentably distinct because Group I merely requires cyclodextran, sodium salicylate, and NaOH. See independent claim 1. However, the kit in Group II further includes a plurality of reagents including 25-OH-D coupled to a solid phase. These regents are not found in the kit of Group I. Accordingly, the kits contain different reagents and are therefore patentably distinct.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Please note that the classifications in the restriction are illustrative only and **do not** represent all the classes and subclasses which must be searched for each invention; nor is the search limited to issued US patents, but rather includes foreign patents and applications as well as literature searches.

5. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 86-93 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

OBJECTIONS WITHDRAWN

Drawings

6. Applicants have removed the illustration of Table I from the specification. Table I has been included in the drawings as figure 1B. Both figures 1A and 1B are included in the brief description portion of the specification. Accordingly the objection to the drawings is withdrawn.

Oath/Declaration

7. An executed supplemental Declaration has been received 10/15/03, therein obviating the deficiencies of record in paper #13. The objection is withdrawn.

Specification

8. The specification has been amended to correct errors. Therefore, the objection to the specification is withdrawn.

9. The rejections of record in paper #13 not reiterated herein are withdrawn.

NEW GROUNDS OF REJECTION NECESSITATED BY AMENDMENT

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-7, 11-12, 15, 17-20, 22, 25-41, and 85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 1 recited the use of the kit to determine the concentration of a vitamin D component. This is vague and indefinite because the use of the kit is not given patentable weight. Patentability exists in the kit components regardless of their utility. If this is intended to limit the kit product, it must be written to result in a structural limitation. Appropriate correction is required.

B. Claims 5, 6, and 7 are unclear because vitamin D is not part of the claimed kit, therefore the claims fail to further limit the kit of claim 1. In other words claims 5, 6, and 7 do not recite regents included in the kit. Please clarify.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 1-6, 11, 12, 15, 17-20, 22, 23, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ullman et al. (U.S. Patent #4,121,975) in view of Foster et al. (U.S.Patent#4,444,879).

Ullman et al. disclose the use of the reagent combination recited in claim 1. Specifically, the sample of interest is combined with a reagent solution comprising 0.5N sodium hydoxide (NaOH), 5% α-cyclodextrin and 5mg/ml salicylate. See column 3 lines 18-23. This reads on the instant claims because 0.5N NaOH is the same as 0.5M NaOH and the claimed concentration of cyclodextrin is between 0.01 to about 5%. With respect to the teaching of sodium salicylate it is noted that the patent of Ullman et al. teaches that the preferred releasing reagent is salicylate. Column 2 line 44. Further "the salicylate will be present as the alkali metal salt solution". The preferred alkali metal bases include sodium. See column 2 lines 60-64. Accordingly, the combination of sodium salicylate is disclosed by Ullman et al.

With respect to the reagents being utilized to detect a vitamin D component, it is noted that this is the intended use for the kit/product and therefore is not given patentable weight.

A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Further, a "use" can only be properly claimed as a process or method. 35 USC 100(b), 101. See Clinical Products v. Brenner, 255 F.Supp.131, 149 USPQ 475, 477 (DDC 1966). *In re Thuau*, 1943 CD 390.

Ullman et al. differs from the instant invention in not specifically teaching the assay reagents as a kit.

However, kits are well known embodiments for assay reagents. Foster et al. (U.S. Patent #4,444,879) describe one example. In their patent kits including the reactant reagents, a microplate, positive controls, negative controls, standards, and instructions are taught. See figure 6, and column 15, lines 10-34.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the detection assay reagents as taught by Ullman et al. and format them into a kit because Foster et al. teach that it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit. Further, the reagents in a kit are available in pre-measured amounts, which eliminates the variability that can occur when performing the assay.

One of ordinary skill in the art would have been motivated to manufacture kits comprising the reagents known in the prior art in order to take advantage of the economic benefits.

II. Claims 7, 25-27 and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ullman et al. (U.S. Patent #4,121,975) in view of Foster et al. (U.S.Patent#4,444,879) as applied to claims 1-6, 11, 12, 15, 17-20, 22, 23, and 41 above, and further in view of DeLuca et al. (US Patent #5,064,770).

Please see Ullman et al. (U.S. Patent #4,121,975) in view of Foster et al. (U.S.Patent#4,444,879) as set forth above.

Ullman et al. (U.S. Patent #4,121,975) in view of Foster et al. (U.S.Patent#4,444,879) do not teach the utility of a host component binding partner complex (double antibody) kit configurations.

DeLuca et al. teach methods and kits for assay 1,25 dihydroxy vitamin D receptor protein (another vitamin D metabolite/component). The kits comprise a first radioactively labeled antibody capable of binding to a first epitope of the vitamin receptor D protein (partner component) and a second antibody capable of binding to a second epitope of the vitamin D receptor(detecting composition). Column 2 lines 33-65 and claims 4-6.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ an additional binding composition specific for the host (such as Vitamin D) as taught by DeLuca et al. in the reagent kit of Ullman et al. (U.S. Patent #4,121,975) in view of Foster et al. (U.S.Patent#4,444,879) because DeLuca et al. disclosed that his assay was sensitive, reproducible, easy to use, and useful in connection with crude samples from mammalian sources. Column 2 lines 6-10. DeLuca et al. teach the anchoring of molecules like vitamin D via a partner component helps to stabilize the receptor, eliminated excess unbound reagent, and prevents denaturing. Column 2 lines 44-60.

III. Claims 28-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ullman et al. (U.S. Patent #4,121,975) in view of Foster et al. (U.S.Patent#4,444,879) and further in view of DeLuca et al. (US Patent #5,064,770) as applied to claims 7, 25-27 and 38-40 above, and further in view of Nargessi et al. (US Patent #5,770,176).

Ullman et al. (U.S. Patent #4,121,975) in view of Foster et al. (U.S.Patent#4,444,879) and further in view of DeLuca et al. are set forth above.

Ullman et al. (U.S. Patent #4,121,975) in view of Foster et al. (U.S.Patent#4,444,879) and further in view of DeLuca et al. differ from the instant invention in not teaching acridinium as a label and magnetic particles as a separator component.

However Nargessi et al. disclose methods and kits involved in the measurement of receptors. See abstract and figure 1. The receptors include Vitamin D. See column 8. lines 23-33. The assay and kits teach the utility of magnetic particles (column 19 lines 9-11) and acridinium (Column 20 lines 27-28).

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take employ magnetic particles and acridinium labels as taught by Nargessi in the detection kit of Ullman et al. (U.S. Patent #4,121,975) in view of Foster et al. (U.S.Patent#4,444,879) and further in view of DeLuca et al. because Nargessi taught that magnetic particles were particularly preferable in automated procedures. Column 19 line 9-11. While the reagents could be labeled in any manner directly or indirectly as long a visible signal was generated. Column 19 lines 60-64. Preferred labels were luminescent signals (such as acridinium) because simplicity, analytical sensitivity, further allowing for the measurement of small amounts of analytes. Column 10 lines 15-28.

Response to Arguments

Applicant contends that the Office indicated that a kit comprising at least NaOH, cyclodextrin, and sodium salicylate appear to be allowable over the prior art of record in paper #13. However, after subsequent consideration US Patent #4,121,975 to Ullman et al. was found and communicated to Applicant as intervening prior art. In response it is noted, that there us nothing unusual, certainly, about an Examiner changing view points as the prosecution of a case progresses, and, so long as the rules of the Patent Office Practice are duly complied with, an applicant has no legal complaint because of such change in view. *In re Ellis*, 31 USPQ 380; *In re Becker*, 40 USPQ 624.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that Kobayashi does not teach or suggest the combination of NaOH and salicylate. This argument was carefully considered and found persuasive. Accordingly, Ullman et al. in view of Foster et al. were added to make obvious the combination of the reagents.

Applicant contends that Atkinson was non analogous art which measure salicylate instead of employing salicylate. This argument was carefully considered and found persuasive. The reference to Atkinson has been withdrawn from the rejections.

Applicant contends that Ullman et al. discloses a composition to measure thyroxine and not 25-OH-D. This argument was carefully considered but not found persuasive because a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

12. For reasons aforementioned, no claims are allowed.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (703) 872-9306, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see httpr//pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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